Food and Drug Administration

[Docket No. 93N–0405]

New Monographs and Revisions of Certain Food Chemicals Codex Monographs; Final Approval by the Committee on Food Chemicals Codex; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of certain new and revised Food Chemicals Codex monographs. These monographs have been approved by the National Academy of Sciences/Institute of Medicine (NAS/IOM) Committee on Food Chemicals Codex (the committee) for inclusion in the fourth edition of the Food Chemicals Codex, which is scheduled for release in March 1996. Until the fourth edition is published, copies of the monographs may be obtained upon request to NAS/IOM.

ADDRESSES: Submit written requests for copies of the Food Chemicals Codex monographs to the NAS/IOM Committee on Food Chemicals Codex, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418.

FOR FURTHER INFORMATION CONTACT:

Fatima N. Johnson, Committee on Food Chemicals Codex, Food and Nutrition Board, National Academy of Sciences, 2101 Constitution Ave. NW., Washington, DC 20418, 202–334–2580; or

Paul M. Kuznesof, Center for Food Safety and Applied Nutrition (HFS–247), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3009.

SUPPLEMENTARY INFORMATION: FDA provides research contracts to NAS/IOM to support the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before the inclusion of any specifications in a Food Chemicals Codex publication, an announcement is published in the **Federal Register** inviting all interested parties to comment and to make suggestions for consideration.

In the **Federal Register** of January 4, 1994 (59 FR 307), FDA announced that the committee was considering several new monographs and monograph revisions. The following monographs have now been approved by the committee for inclusion in the fourth edition:

I. New Monographs

Acesulfame potassium
Glyceryl monooleate

II. Current Revised Monographs

Calcium carbonate (lead and heavy metals limits)
Caramel (numerous revisions)
Carnauba Wax

No changes from what was previously offered for public review in the **Federal Register** of January 4, 1994, resulted from comments received on these monographs. Individual copies of these monographs are available from NAS/IOM (address above) until the fourth edition of the Food Chemicals Codex is published in 1996.

FDA emphasizes, however, that it will not consider adopting and incorporating any of the committee's new monographs and monograph revisions into FDA's regulations without ample opportunity for public comment. If FDA decides to propose the adoption of changes and new monographs that have received final approval by the committee, such opportunity for public comment will be announced in a notice published in the **Federal Register**.

Dated: February 26, 1995.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–5673 Filed 3–7–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB) for Clearance

AGENCY: Health Care Financing Administration, HHS.

The Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to OMB the following proposals for the collection of information in compliance with the Paperwork Reduction Act (Public Law 96–511).

1. *Type of Request:* Extension; *Title of Information Collection:* Survey Report Form; *Form No.:* HCFA–1557; *Use:* This survey form is an instrument used by the State agency to record data collected in order to determine compliance with the Clinical Laboratory Improvement Amendments. This information is needed for laboratory certification and recertification; *Respondents:* Business or other for profit, Federal Government, State or local government; *Number of Respondents:* 30,225; *Total Annual Responses:* 30,225; *Total Annual Hours Requested:* 16,321.5.

2. *Type of Request:* Extension; *Title of Information Collection:* Clinical Laboratory Improvement Amendments Application forms; *Form Nos.:* HCFA–14 and –116; *Use:* The application must be completed by entities performing laboratory testing on human specimens for health purposes; *Respondents:* Business or other for profit, Federal Government, State or local government; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours Requested:* 20,000.

3. *Type of Request:* New; *Title of Information Collection:* Quality Assurance for Phase II of the Home Health Agency Prospective Payment Demonstration; *Form No.:* HCFA–R–74; *Use:* This instrument will be used to collect information to implement an outcome-based quality assurance program to monitor the quality of care provided by agencies participating in Phase II of the Home Health Agency Prospective Payment Demonstration; *Respondents:* Business or other for profit, nonprofit institutions; *Number of Respondents:* 29,427 (episodes); *Total Annual Responses:* 58,854; *Total Annual Hours Requested:* 10,152.

Additional Information or Comments: Call the Reports Clearance Office on (410) 966–5536 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: February 27, 1995.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 95–5572 Filed 3–7–95; 8:45 am]

BILLING CODE 4120–03–P

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Coagulation, Platelets and Thrombosis in Sickle Cell Disease.

Date: March 29, 1995.

Time: 8:30 a.m.

Place: Hyatt Regency, Bethesda, Maryland.

Contact Person: Dr. Lynn Amende, 5333 Westbard Avenue, Room 5A10, Bethesda, Maryland 20892, (301) 594–7480.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Cytokine Effect on Hematopoiesis in AIDS Animal Models.

Date: May 1–2, 1995.

Time: 7 p.m.

Place: Holiday Inn, Chevy Chase, Maryland.

Contact Person: Dr. Deborah Beebe, 5333 Westbard Avenue, Room 555, Bethesda, Maryland 20892, (301) 594–7418.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: March 3, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–5643 Filed 3–7–95; 8:45 am]

BILLING CODE 4140–01–M

Uniform Biological Material Transfer Agreement: Discussion of Public Comments Received; Publication of the Final Format of the Agreement

AGENCY: National Institutes of Health (NIH), Public Health Service (PHS), DHHS.

ACTION: Notice.

SUMMARY: Following consideration of public comments, the NIH, as designated lead PHS agency for technology transfer activities, is issuing the final version of the Uniform Biological Material Transfer Agreement (''UBMTA'') to be used by participating public and nonprofit organizations, an implementing letter to memorialize individual exchanges of biological material under the UBMTA, and a simple letter agreement for transferring nonproprietary biological materials among public and nonprofit organizations. For-profit organizations may also choose to adopt these agreements as well. The PHS recommends that the UBMTA be considered for general use in the exchange of biological material for research purposes among public and nonprofit entities.

FOR FURTHER INFORMATION CONTACT: Carol C. Lavrich, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804, phone: 301–496–7735 ext. 287, fax: 301–402–0220.

Background

Open access to the results of federally-funded research is a cornerstone of PHS's research policy. In the case of many research projects, this includes not only access to information provided through publications, but also access to biological research materials necessary to replicate or build on the initial results. Frequently, the exchange of research materials between scientists in separate organizations involves case-by-case negotiation of material transfer agreements (''MTAs''). In order to guide and facilitate the increasing number of such transfers, PHS issued in 1988, a ''Policy Relating to Distribution of Unique Research Resources Produced with PHS Funding'' (NIH Guide for Grants and Contracts, Vol. 17, No. 29, September 16, 1988: pg. 1; also published at pp. 8–25–8–26 of the PHS Grants Policy Statement, DHHS Publication No. (OASH) 94–50,000 (Rev.) April 1, 1994. This was followed in 1989 by adoption of a standard Material Transfer Agreement form for use by PHS scientists. MTAs are important because they require the recipient to exercise care in the handling of the materials, to maintain control over the distribution of the materials, to acknowledge the provider in publications, and to follow relevant PHS guidelines relating to recombinant DNA, protection of human subjects in research, and the use of animals. However, while most other organizations have adopted some standard material transfer agreement form, they are not all consistent.

Issue

Several issues have affected the sharing of research materials. These include delays in sharing of materials while conducting unnecessarily extensive negotiations on individual MTAs, required grants of invention rights to improvements to the materials or to inventions made using the materials, and required approval for publication. The negotiation of these complex issues has resulted in significant delays in sharing materials, undue administrative barriers to sharing, and in some cases, lack of availability of materials for further research by federal grantees. (For reports and discussion of these issues, please refer to The New Biologist, Vol. 2, No. 6, June 1990: pp 495–497; and Science, Vol. 248, 25 May, 1990: pp 952–957).

Proposal

The PHS, in conjunction with representatives of academia and industry, has coordinated the development of a proposed uniform biological material transfer agreement (''UBMTA'') to address concerns about contractual obligations imposed by some MTAs and to simplify the process of sharing proprietary materials among public and nonprofit organizations. Since 1990, the Association of University Technology Managers (''AUTM''), and many individuals representing universities, law firms, and industry, have played leadership roles in furthering the development of common materials sharing practices. The consistent use of the UBMTA by public and nonprofit organizations could reduce the administrative burden of sharing materials as investigators come to rely on common acceptance of its terms by cooperating organizations.

The PHS recommends that the UBMTA be considered for general use in the exchange of materials for research purposes among public and nonprofit organizations. For-profit organizations may also choose to adopt this agreement as well. While use of the UBMTA may not be appropriate for every material transfer, if used for the majority of transfers, it could set standards for materials sharing that would be of long-term benefit to the research enterprise and to the public health.

As a further suggestion to simplify the process of materials sharing, it is proposed that the UBMTA be approved at the organizational level, and handled in a master agreement or treaty format, so that individual transfers could be made with reference to the UBMTA, without the need for separate negotiation of an individual document to cover each transfer. As a result, transfers of biological materials would be accomplished by an Implementing Letter (see sample) containing a description of the material and a statement indicating that the material was being transferred in accordance with the terms of the UBMTA. The Implementing Letter would be executed by the provider scientist, the recipient scientist, and any other authorized official(s) of the provider or recipient organization who might be required to sign on behalf of the organization. Thus, sharing of materials between organizations, each of which had executed the UBMTA, would be significantly simplified. At the same time, any organization would retain the